

# STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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September 10, 2002

## CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF	)	CERTIFICATE OF NEED
	)	APPLICATION
	)	NO. 02-14
Honolulu Open Medical Imaging, LLC	)	
	)	
Applicant	)	
	)	DECISION ON THE MERITS
	)	

## DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 02-14 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Oahuwide Certificate of Need Review Committee, Certificate of Need Review Panel and Statewide Health Coordinating Council, hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 02-14.

I

## BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of a stationary 0.7 Tesla, high-field, open Magnetic Resonance Imaging service at 1010 South King Street, Honolulu at a capital cost of \$2,652,553.
2. The applicant is a private for-profit limited liability corporation incorporated pursuant to the laws of the State of Hawaii.

3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).

4. On July 2, 2002, the applicant filed with the Agency a Certificate of Need application for the establishment of a stationary 0.7 Tesla, high-field, open Magnetic Resonance Imaging service at 1010 South King Street, Honolulu at a capital cost of \$2,652,553. (the "Proposal") On July 10, 2002, the Agency determined that the Application was incomplete and requested additional information. On July 18, 2002 the applicant submitted additional information. On July 24, 2002 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #02-14. The applicant amended its application on the August 13, 2002 and August 22, 2002.

5. The period for Agency review of the application commenced on July 26, 2002, the day notice was provided to the public in the *Honolulu Star-Bulletin*.

6. The Oahuwide Certificate of Need Review Committee met at a public meeting on August 9, 2002 and recommended approval of this application by a vote of 5 in favor and none opposed. During member discussion at the meeting, the Committee suggested that additional information regarding the following would be useful:

- The application's relationship to the specific disease chapters of H2P2 (Chapters IV – XI)
- Inclusion of statistics on the number of obese and claustrophobic patients requiring the use of an open MRI unit
- Clarification on how the proposed unit will improve the existing health care system i.e. medical outcomes rather than the reducing the waitlist time for an MRI procedure which is an issue of convenience.

7. The application was reviewed by the Certificate of Need Review Panel ("Panel") at a public meeting on August 15, 2002. The Panel recommended approval of the Proposal by a vote of 7 in favor and none opposed. During member discussion at the meeting, the Panel suggested that additional information regarding the following would be useful:

- More detail as to how the proposal directly relates to the specific disease chapters of H2P2 would be useful
- Further clarity regarding charity care
- How the applicant's projected patient mix compared to that of the proposed MRI service approved for Yeoh and Muranaka (Cert. #01-12)

Although no data was available to allow a direct comparison of the patient mix, the Panel compared each of the applicants' payment sources.

Members commented that the payment source profiles were different and,

although not conclusive, appeared to indicate different patient mixes for the two MRI services.

8. The Statewide Health Coordinating Council review met at a public meeting on August 9, 2002 and recommended approval of this application by a vote of 14 in favor and none opposed.

9. This application was reviewed in accordance with Section 11-186-15, HAR:

"(a) The agency shall consider the following criteria in the review of an application for a certificate of need:

- (1) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, are likely to have access to those services;
- (2) In the case of reduction or elimination of a service, including the relocation of a facility or service:
  - (A) The need that the population presently served has for the service;
  - (B) The extent to which that need will be met adequately by the proposed relocation or by alternative arrangements; and
  - (C) The effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care;
- (3) The probable impact of the proposal on the overall costs of health services to the community;
- (4) The probable impact of the proposal on the costs of and charges for providing health services by the applicant;
- (5) The immediate and long term financial feasibility of the proposal;
- (6) The applicant's compliance with federal and state licensure and certification requirements;
- (7) The quality of the health care services proposed;
- (8) In the case of existing health care services or facilities, the quality of care provided by those facilities in the past;
- (9) The relationship of the proposal to the state health services and facilities plan and the annual implementation plan;
- (10) The relationship of the proposal to the existing health care system of the area;
- (11) The availability of less costly or more effective alternative methods of providing service;
- (12) The availability of resources (including health personnel, management personnel, and funds for capital operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the state health services and facilities plan and the annual implementation plan.

(b) Criteria for review of an application may vary according to the purpose for which particular review is being conducted or according to the type of health care service being reviewed."

10. Pursuant to Section 323D-43(b), HRS:

“(b) No Certificate shall be issued unless the Agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs.”

11. Burden of proof. Section 11-186-42, HAR, provides:

“The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence.”

II

**FINDINGS OF FACT**

A. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE STATE PLAN (H2P2)

Vision and Guiding Principles (Chapter II)

12. In relation to the goals and objectives of H2P2, the applicant states at page A-3 of its application:

“All patients of Hawaii will have access to the outpatient MRI services. The open MRI does not limit or prohibit the use of the MRI on certain patients such as those that are claustrophobic or of a larger size. Increasing the availability of these services to more patients will help to reduce the health disparities among Hawaii residents.”

“MRI procedures help to early detect and diagnose treatable diseases, reduce the effects of chronic disease and prolong health related quality life, reduce morbidity and pain through timely and appropriate treatment and establish health care delivery systems that are cost-effective and foster improved access to quality health care services. Each of these is an objective as provided in H2P2 that supports the stated goals.”

13. In relation to the basic principals the health care delivery system, the applicant states, at page A-4 of its application, “the addition of outpatient MRI

services to Hawaii's health care delivery system will increase the comprehensiveness, cost-effectiveness, coordination and responsiveness of the system."

14. With respect to the H2P2 desired characteristic of supporting collaboration between health care providers, the applicant states at page A-5 of its application:

"The outpatient facility is being developed in collaboration with Straub Clinic and Hospital. Due to the recent merger of Hawai'i Pacific Health with Straub Clinic and Hospital and Wilcox Memorial Hospital, the collaboration of this effort extends beyond just one hospital and an outpatient facility. Such collaboration improves the likelihood of success as the providers work together to meet the needs of the community without duplicating efforts and increasing costs."

15. In relation to the H2P2 critical elements of the health care delivery system, the applicant states at pages A-6 and A-7 of its application:

"Physical access will not be an issue as there is sufficient parking, handicap access and access by public transportation. The services will also be accessible to all individuals that are properly referred by a physician and who meet the criteria for a MRI procedure (i.e., a MRI procedure may not be appropriate for a patient with metal implants).

MRI procedures also help to reduce the need for invasive diagnostic tests which reduces the pain, risk and recovery time for the patient.

The use of MRI procedures on an outpatient basis is a cost-effective means of providing MRI procedures. The amount of capital, overhead and the overall costs of an outpatient facility is generally less costly than a hospital-based unit due to the overall cost of operating a hospital."

16. In relation to the H2P2 capacity thresholds, the applicant states at Page A-8 of its application:

"H2P2 provides capacity thresholds for MRI services. The threshold for a new unit or service is a minimum of 1,500 procedures per year for all providers in the service area with the new provider meeting the minimum threshold by the third year of operations. The threshold for an existing unit or service is a minimum of 2,750 procedures per year for the provider.

Based on the current utilization of MRI procedures by providers on Oahu, all of the providers are meeting the minimum threshold of 1500 procedures per year."

17. The applicant projects that it will perform 3999 procedures in Year 3 of its Proposal.

18. At page A-8 of its application, the applicant states that:

"Based on estimates of demand and supply, the addition of an outpatient MRI facility will not reduce the annual utilization at each of the existing units below the 1,500 threshold."

#### Diseases and Conditions (Chapters IV-XI)

19. The applicant states that for many of the diseases or conditions in Chapters IV through XI of H2P2, its MRI service will be part of the detection and treatment process for the patient.

20. The applicant states that its Proposal will provide "the most significant impact" on the following chapters of H2P2:

##### Cancer (Chapter V)

- The applicant states that the MRI will assist in the detection of cancer due to the ability of the MRI to better differentiate between soft tissue and bony matter. The applicant also states that its Proposal will assist with the treatment of cancer by monitoring the changes in cancer as treatment progresses.

##### Diabetes (Chapter VI)

- The applicant states that its Proposal can assist with the detection and treatment of complications resulting from diabetes including nerve disease, amputations, heart disease and stroke.

##### Heart disease and stroke (Chapter VII),

- The applicant states that MRI units can be used for the detection and prevention of cardiac conditions.

##### Dental (oral) health (Chapter IX)

- The applicant states that its Proposal will assist in the detection and treatment of oral tumors, degenerative joint disease and other indications of TMJ.

Preventable injuries and violence (Chapter VIII)

- The applicant states that MRI services can be used to detect accidental and non-accidental injuries, particularly injuries affecting joints and the spine that may occur in infants, children and adolescents whether caused by accidents (i.e., sports injuries) or non-accidents (i.e., child abuse).
- The applicant states that its Proposal will assist in the detection and treatment of muscle and tendon injuries, injuries to bones, joints and hips.

21. The Agency finds that this criterion has been met.

**B. REGARDING NEED AND ACCESSIBILITY CRITERIA**

22. The applicant states that the H2P2 threshold for a new MRI unit or service is a minimum of 1,500 procedures per year for all service providers in the service area with the new provider meeting the minimum threshold by the third year of operations.

23. The applicant states that, based upon the current utilization of MRI procedures by providers on Oahu, all of the providers are meeting the minimum threshold of 1500 procedures per year.

24. The applicant projects that it will perform 3999 procedures in Year 3 of its Proposal.

25. The applicant states that the number of MRI procedures performed on Oahu from 1996 to 2000 were as follows: 1996 – 18,724, 1997 – 20,108, 1998 – 25,193, 1999 – 30,048 and 2000 – 34,012.

26. The applicant states that the average annual growth in MRI procedures on Oahu has been approximately 16% each year from 1996 to 2000.

27. The applicant projects that, "if the average increase is applied to the number of procedures performed in the Year 2000, the number of procedures for the Oahu residents from 2002 through 2005 would be as follows: 2002 – 45,760, 2003 – 53,080, 2004 – 61,570, 2005 – 71,420.

28. The applicant states that "assuming demand increases by an average of 16% each year and the MRI units continue to provide the current number of procedures, the estimated yearly deficit in the supply of MRI procedures would be as follows: 2002 – 11,748, 2003 – 19,068, 2004 – 27,558, 2005 – 37,048."
29. The applicant states that a Certificate of Need application for a new outpatient MRI facility has been approved for Yeoh and Muranaka M.D.'s Inc. and that the said facility anticipates providing "approximately 2000 MRI procedures each year (procedures range from 1500 in the first year to 2200 in the fifth year of operations)."
30. The applicant states that with the addition of 2,000 procedures to available supply, there is still a deficit of over 9,700 procedures in 2002.
31. The applicant states that the Proposed unit will allow physicians to perform MRI assisted breast biopsy procedures and that its unit will be accessible to qualified physicians statewide for this procedure.
32. The applicant states that its MRI service will be accessible to all patients who need outpatient MRI services without discrimination based on income, race, ethnic background, religious affiliation, gender or any other category.
33. The Agency finds that the need and access criteria have been met.

#### C. REGARDING QUALITY AND LICENSURE CRITERIA

34. The applicant states that it will apply for Medicare and Medicaid certification and accreditation by the American College of Radiology.
35. The applicant states that all radiologists contracted to provide services for the Proposal must be board certified in radiology.
36. The applicant states that the MRI services will be provided by qualified MRI technologists who have the proper training and credentials.
37. The applicant states that its Proposal will improve quality of care by making MRI services more accessible to patients who are in need of a high field open MRI unit and are claustrophobic or are too large for a closed MRI unit.
38. The applicant states that for large or claustrophobic patients, certain procedures including neurological procedures can only be done using an open high field MRI unit.



39. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

40. The applicant states that the overall cost of health care should decrease as the cost of outpatient MRI services is less than the cost of hospital-based MRI services. The applicant also states that as a freestanding, outpatient facility, it has the ability to manage staffing of the facility based on service volume to further control operating costs.

41. With respect to the financial feasibility of the Proposal, the applicant projects that, in Exhibit D-2 of its application, the excess funds from operations (after payment of principal and interest on the debt associated with the purchase of the MRI equipment) will be \$6,975 in year one and \$420,349 in year three of the Proposal.

42. With respect to the availability of less costly or more effective alternative methods of providing service, the applicant states that other radiology diagnostic tools do not provide physicians with the same type and quality images as MRI.

43. The Agency finds that cost and financial criteria have been met

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

44. The applicant states that its proposal will fill a gap in the existing healthcare delivery system by providing physicians with an imaging option that does not currently exist – an open high field unit.

45. The applicant states that its unit will be available to qualified radiologists throughout the State of Hawaii.

46. With respect to the effect that the proposal will have on existing health care providers, the applicant states that its Proposal "is not anticipated to have a negative impact on other health care services." The applicant states that there is currently more demand for the services than the existing MRI units can provide.

47. The Agency finds that this criterion has been met.

F. REGARDING THE AVAILABILITY OF RESOURCES

48. With respect to personnel resources, the applicant states its Proposal will require the following: a MRI technologist, transcriptionist, receptionist/ administrative assistant, records administrator and marketing representative. The applicant states that the individuals with the proper skills, experience and knowledge are available. The applicant states that the services of radiologists will be secured through contracts.

49. With respect to financial resources, the applicant states that the initial funding to develop and establish the operations, which includes the purchase of the MRI equipment and start up working capital, will be provided by equity contributions from its members, MD Services and Straub Imaging. The applicant states that financing for the Proposal has already been secured.

50. The applicant states that it will have sufficient cash flow from operations to pay for operational needs as well as debt payments.

51. The Agency finds that the applicant has met this criterion.

### III

#### CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 02-14 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Oahuwide Certificate of Need Review Committee, Certificate of Review Panel, and Statewide Health Coordinating Council and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (2) The cost of the proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Honolulu Open Medical Imaging, LLC for the proposal described in Certificate Application No. 02-14. The maximum capital expenditure allowed under this approval is \$2,652,553.

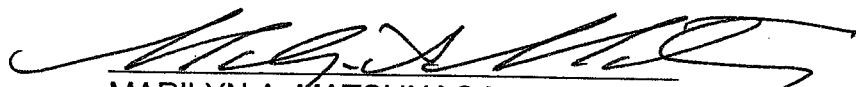
WRITTEN NOTICE

Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 of the Agency's Certificate of Need Program rules. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

DATED: September 10, 2002  
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

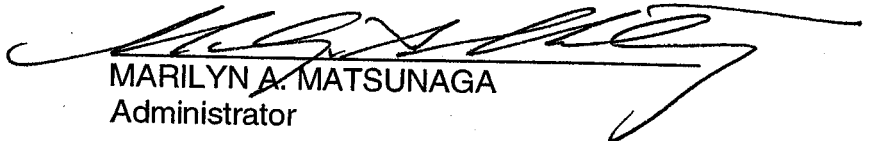
  
MARILYN A. MATSUNAGA  
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on September 10, 2002.

Steven Krieger  
Chief Executive Officer  
Honolulu Open Medical Imaging, LLC  
3396 Willow Lane, Suite 100  
Westlake Village, CA 91361

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

  
MARILYN A. MATSUNAGA  
Administrator